

REMARKS

The present communication responds to the Final Office action of December 7, 2007 in which the Examiner rejected claims 30 and 31. Claims 30 and 31 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent 6,013,029 (“Korf et al.”) in view of U.S. Patent 5,607,390 (“Patsalos et al.”), U.S. Patent 6,463,312 (“Bergveld et al.”) and U.S. Patent 5,640,954 (“Pfeiffer et al.”).

The claim rejections are traversed for at least the reasons articulated below and reconsideration is requested.

Rejection under 35 U.S.C. § 103

Claims 30 and 31 were rejected under 35 U.S.C. § 103(a) as unpatentable over Korf et al. in view of Patsalos et al., Bergveld et al. and Pfeiffer et al.

Applicant maintains that the § 103 rejection of the claims over Korf in view of Patsalos et al., Bergveld et al. and Pfeiffer et al. is improper for at least the following reasons.

I. Korf teaches against providing a check valve in the flow path

Regarding the combination of Korf et al., Patsalos et al. and Bergveld et al. the Examiner correctly states that the combination does not disclose a valve. (*Office Action, bottom of page 2 to top of page 3*).

Korf et al. discloses a method for monitoring the concentration of substance(s) in body fluid, which employs a low flow rate, and “[d]ue to these low flow rates, a very constant flow can be maintained for a long period of time with simple means, which need no or very little supply energy. In the preferred embodiment, the means for maintaining the flow of the perfusate are of a non-moving type and consist of a waste reservoir 5 containing a fluid absorbing material . . . A separate energy reservoir for the purpose of driving the flow can thus be dispensed with or be very small and light.” (*Korf et al., col. 5, lines 37-50*).

Pfeiffer et al. discloses a check valve 90 in an apparatus for continuously monitoring the concentration of a metabolite.

Applicant maintains that the use of a check valve in Korf et al. is unnecessary because perfusate constantly flows from the interface to the detector. (*Korf et al, col. 5, line 36*).

Applicant also maintains that the use of a check valve is contraindicated by Korf et al., i.e., Korf et al. teaches away, because no power source or a very small power source is contemplated for moving perfusate through the flow path. In Korf's method of monitoring body fluids that employs low flow rates (e.g. less than 20 μ l/hour), by employing moving parts in the flow path such as a check valve from Pfeiffer et al., additional energy would be required to maintain the check valve in an open position thus allowing the perfusate to flow. It is an object of Korf et al. to do without a power reservoir or have one that is very small and light. Adding movable parts to the flow path in Korf et al. increases the amount of energy required to operate the flow path and vitiates one of its main objectives: eliminating or greatly reducing supply energy.

Not only does the use of the check valve increase the amount of energy required to operate the flow path of Korf et al., the definition of "valve" includes a movable part. However, Korf et al. teaches away from movable parts for maintaining a constant flow.

A definition of "valve" is: any of numerous mechanical devices by which the flow of liquid, gas, or loose material in bulk may be started, stopped, or regulated by a movable part that opens, shuts, or partially obstructs one or more ports or passageways; *also* : the movable part of such a device. (*Merriam-Webster's Online Dictionary, last accessed 3/4/2008*).

In addition to the examples provided by Korf et al. to describe means for maintaining the flow of the perfusate that are of non-moving type, (*Korf et al., col. 5, line 38 to col. 6, line33*), Korf et al. discloses that "there are many other possibilities for providing non-moving means for maintaining a constant flow, such as a capillary reservoir forming the waste facility, an osmotic membrane and a heater for warming up an expansion element adjacent the supply reservoir."

The Office Action states that, “a one way valve could be a mechanical valve and require no power” and also that “minimal power increase necessitated by the valve would be outweighed by the gain in safety gained from using the valve to prevent backflow of fluids,” (*Office Action, page 3*). Applicant agrees that a one way valve could be a mechanical valve, however, one skilled in the art would still not choose to combine a mechanical valve that requires either no power increase or even a minimal power increase with the disclosure of Korf et al. because the valve includes movable parts.

Korf et al. fails to disclose or suggest, provide any motivation or an expectation of success to one skilled in the art to select a mechanical valve for positioning in the flow path. To the contrary, Korf et al. emphasizes the necessity of providing non-moving means for maintaining a constant flow. Since a valve, by definition includes a movable part, one skilled in the art would not choose to place a valve, whether mechanical or otherwise, in the flow path of Korf et al.

Accordingly, adding a check valve such as the one in Pfeiffer et al. is contraindicated by the teachings of Korf et al.

II. The sensor adjacent to the valve is not disclosed or suggested in the cited references alone or in combination

Korf et al. in view of Patsalos et al., Bergveld et al. and Pfeiffer et al. do not disclose or suggest a “sensor is positioned adjacent to the valve” as recited in claim 30.

Claim 30 *inter alia* states: “an outlet portion positioned on the upper surface of the supporting plate and coupled to the discharge tube at a joint portion positioned on the upper surface of the supporting plate, wherein the dialysis fluid containing constituents flows from the discharge tube to the outlet portion through the joint portion; a valve positioned in the discharge tube adjacent to the joint portion for preventing a reverse flow of the dialysis fluid into the discharge tube; and a sensor for measuring attributes of fluids in the body, wherein the sensor is positioned adjacent to the valve in the joint portion between the discharge tube and the outlet portion.”

The Office Action states that, “the question is whether the combination has the feature [the sensor adjacent to the valve] . . . in the combination the valve would be adjacent to the sensor.” Applicant disagrees that the combination of Korf et al., Patsalos et al., Bergveld et al. and Pfeiffer et al. discloses that the valve would be adjacent to the sensor.

Regarding the combination of Korf et al., Patsalos et al. and Bergveld et al. the Examiner correctly states that the combination does not disclose a valve. (*Office Action, bottom of page 2 to top of page 3*).

Pfeiffer et al. discloses a check valve 90, positioned in the dialysate tube 14, which self-locks upon backflow of measuring dialysate in the direction of the microdialysis probe. In Pfeiffer et al., check valve 90 of the metabolite monitoring apparatus is positioned on dialysate tube 14, but it is not positioned adjacent to a sensor.

As shown in Fig. 1 of Pfeiffer et al., once the perfusate passes check valve 90, it reaches junction 20, which introduces enzyme solution 38 to the perfusion fluid. The mixture then passes through junction 40 in such a way that “[t]he measuring dialysate flow is let through the flow chamber 16 which is interconnected in the measuring dialysate tube 15 by way of junctions 40, 42, [and] the measuring dialysate flow is led past sensor 26.” (*Pfeiffer et al., col. 5, lines 2-6.*)

Applicant maintains that Pfeiffer et al. does not disclose a valve positioned adjacent to the sensor as recited in claim 30. Furthermore, Pfeiffer et al. does not disclose alternative configurations of the metabolite monitoring apparatus in which check valve 90 may be positioned adjacent to the sensor.

Fig. 1 shows that in Pfeiffer et al. the perfusate passes check valve 90 and then further downstream there is a junction 20, which allows for an addition of enzyme solution into the flowing perfusate, and further downstream there is another junction 40, and even further downstream there is a sensor 26. It can hardly be said that the sensor 26 of Pfeiffer et al. is *adjacent* to check valve 90 of Pfeiffer et al. To the contrary, the sensor 26 is far downstream of the check valve 90. Furthermore, there are two junctions, junction 20, and junction 40, between

the check valve 90 and the sensor 26, one of the junctions even adds another solution to the perfusate flow.

The check valve 90 of Pfeiffer et al. and the sensor 26 of Pfeiffer et al., cannot be described as adjacent (immediately following one another) at least because of the two intervening junctions.

Korf et al. does not disclose a check valve. The combination of Korf et al. with Pfeiffer et al. would introduce two junctions and the increased flow of an additional fluid to the perfusate of Korf et al. Therefore, the combination of Korf et al., Patsalos et al., Bergveld et al. and Pfeiffer et al. fails to disclose or suggest, provide any motivation or an expectation of success to one skilled in the art to select a sensor positioned adjacent to the valve. Furthermore, as recited in claim 30, the sensor is positioned adjacent to the valve in the joint portion between the discharge tube and the outlet portion. The combination of the cited art would not place the sensor in a joint portion adjacent to the valve as recited in claim 30. Instead, Pfeiffer et al. discloses two junctions in between the valve and the sensor. The sensor of Pfeiffer et al. does not reside in a joint portion adjacent to the valve.

III. *The Examiner uses impermissible hindsight to piece together the cited references*

It is noted in the Office Action “that there is motivation for each combination, particularly in view of the language in the KSR decision handed down by the Supreme Court.” (*Office Action, page 4*).

Applicant disagrees that there is motivation for each combination.

As discussed above, the combination of the cited references does not disclose or suggest, provide any motivation or an expectation of success to one skilled in the art to select a joint portion positioned on the upper surface of the supporting plate, wherein the dialysis fluid

containing constituents flows from the discharge tube to the outlet portion through the joint portion; a valve positioned in the discharge tube adjacent to the joint portion for preventing a reverse flow of the dialysis fluid into the discharge tube; and a sensor for measuring attributes of fluids in the body, wherein the sensor is positioned adjacent to the valve in the joint portion between the discharge tube and the outlet portion as recited in claim 30.

Therefore, Applicant maintains that the present invention has been used as a blueprint for piecing together Korf et al., Patsalos et al., Bergveld et al., and Pfeiffer et al. Accordingly, the Examiner has used impermissible hindsight, and has not established a *prima facie* case of obviousness.

For at least the preceding reasons, the rejection under § 103 should be reconsidered and withdrawn.

Dependent Claim

Claim 31 depends from independent claim 30, and is patentable over the art of record for at least the reasons set forth above, further in view of its additional recitations.

Conclusion

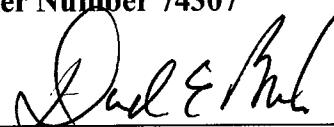
This response is being submitted on or before June 7, 2008, and a request to extend the time to respond until that date is hereby made. The required fee should be charged to Deposit Account No. 04-1420. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application is in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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